Declaration of Product Performance Effectiveness

Product Family: Disposable Channel Cleaning Brush (DCCB)

PriMed Instruments' DCCB models 9115, 9190 and 9192 (DART® Push and Pull Triple Headed Channel Brush) were tested and found to have met and exceeded AAMI TIR30 requirements. Testing was done according to instructions provided in the IFU and method outlined in AAMI TIR30. In the studies conducted by SPS Medical[1][2], the results verify that a protein level of less than 6.4μg/cm² was achieved on the endoscope channels when using PriMed Inst. and leading competitors (e.g. Olympus & Pentax) cleaning brushes, demonstrating each method of cleaning to be efficacious in removing gross amounts of soil. A Protein level of less than 6.4μg/cm² is required by AAMI TIR30:2011 after cleaning, in order to allow the disinfection/sterilization process to achieve the proper sterility assurance level. SPS Medical could not find a significant difference in the total percentage of soil removed between PriMed Inst. and the leading competitor brushes. These studies were completed on Oct. 23, 2012. Table No. 1 below summarize the result from these initial studies.

Table No. 1: Test Result of 9190, 9115 & 9192 brushes compared to equivalent leading competitor brush.

Test Stage	Test No.	Brush Model	Channel Model	Protein Level After Cleaning (μg/cm²)	Positive Control (μg/cm²)	Soil Removal
1	3	PriMed 9190	4051-40	0.00	155.37	100%
		Olympus BW-201T		0.04		99.97%
	4	PriMed 9190	4051-66	0.00	153.91	100%
		Olympus BW-201T		0.25		99.84%
	7	PriMed 9192	4008-07	0.04	139.61	99.97%
		Pentax CS6021T		0.00		100%
	8	PriMed 9192	4008-05	0.34	153.66	99.78%
		Pentax CS6021T		0.08		99.95%
2	1	PriMed 9115	4008-07	0.00	158.91	100%
		Olympus BW-201B		0.00		100%
	2	PriMed 9115	4057-67	0.00	148.22	100%
		Olympus BW-201B		0.91		99.39%
	5	PriMed 9192	4008-07	0.19	150.33	99.87%
		Olympus BW-201B		0.15		99.90%
	6	PriMed 9192	4051-66	0.00	154.88	100%
		Olympus BW-201T		0.14		99.91%

Initial: DV

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1080 Tristar Drive • Unit 14 • Mississauga • Ontario L5T 1P1 • Canada
phone 905 565 0565 • fax 905 565 05665 • www.primedinstruments.com

Update: Design of our 9190 brush was changed from mostly triple-fill bristles to mostly single-fill. Single-fill design allow bristles to be uniformly held-in tight between the twisted wire stem. This will greatly reduce the chance of bristles falling out. Single-fill version of 9190 brushes were tested and found to have met and exceeded AAMI TIR30 testing requirements. Testing conducted by Highpower Vtls[3] concluded that a protein level of less than 6.4μg/cm² was achieved on the endoscope channels when using our 9190 and leading competitor (e.g. Olympus) cleaning brushes, demonstrating each method of cleaning to be efficacious in removing gross amounts of soil. A Protein level of less than 6.4μg/cm² is required by AAMI TIR30:2011 after cleaning, in order to allow the disinfection/sterilization process to achieve the proper sterility assurance level. Highpower Vtls could not find a significant difference in the total percentage of soil removed between PriMed Inst. and the leading competitor brushes. This design change validation was completed on Feb. 14, 2018.

Date of Declaration: MAY 3, 2018

Declared at: MISSISSAUGA, ONTARIO, CANADA

Authorized By (Signature): 

Authorized By (Print): DONG LY
Manager of Regulatory Affairs, PriMed Instruments Inc.

References:

[1]SPS Medical Study No. 1205-159 Protocol and Final Report titled "PriMed Instruments Inc. Comparative Cleaning Study for Disposable Channel Cleaning Brush Stage 1." Cleaning efficacy validation of 9190 & 9192 completed on Jul. 23, 2012.

[2]SPS Medical Study No. 1209-322 Protocol and Final Report titled "PriMed Instruments Inc. Comparative Cleaning Study for Disposable Channel Cleaning Brush Stage 2." Cleaning efficacy validation of 9115 & 9192 completed on Oct. 23, 2012.

[3]Highpower Validation Testing & Lab Services Study No. 1712-821 Protocol and Final Report titled "PriMed Instruments Inc. Comparative Cleaning Study for Disposable Channel Cleaning Brushes." Cleaning efficacy revalidation of 9190 changed to mostly single-fill bristles was completed on Feb. 14, 2018

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